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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,305	07/13/2000	Wolfgang Meier	BioCure 101	4801

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

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DATE MAILED: 10/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/615,305

Applicant(s)

Meier

Examiner

Gollamudi Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 28, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6, 9-14, 16-20, and 27-30 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 9-14, 16-20, and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The request for the extension of time and response filed on 7-28-03 are acknowledged.

Claims included in the prosecution are 1, 3-6, 9-14, 16-20 and 27-30.

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. Claims 1, 3-6, 9-14, 16-20 and 27-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term, 'hollow' does not appear to have support in the specification as originally filed. A careful review of the specification indicates that the central area of the vesicles is either filled with an aqueous or oily medium and therefore, is not hollow.**

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant first argues that the term added is redundant but was added to even more clearly emphasize the differences with the prior art. First of all, if the term is redundant, it should not have been added at all. Secondly, applicant's own exhibit B

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indicates that the term void means hollow or empty space or vacuum. This definition meaning empty space actually supports the examiner's position that since the specification indicates that the central portion is either filled with an aqueous medium or oil medium, it is not empty: that means it is not hollow according to applicant's own exhibit.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what applicant intends to convey by 'a molecule'. What molecule? How can one incorporate just one molecule? Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant submits a definition of the term, 'molecule' (exhibit C) and once again argues that it would be possible to incorporate one molecule such as one membrane protein. It would appear that there is a misunderstanding. It is understandable to one can incorporate on specific membrane protein. However, 'one specific membrane protein' is still made of several molecules and what applicant is incorporating is several molecules of one specific protein and not a single molecule of that

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specific protein. The examiner had already suggested amending this term to recite ‘an active agent’ or similar expression.

Claim Rejections - 35 USC § 102

- 5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

- 6. Claims 1, 10, 12, 17 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Pluyter (6,008,184).**

Pluyter discloses vesicles containing triblock polymers A-B-A wherein A is water soluble polymer and B is water insoluble polymer (note col 2, line 25 et seq., col. 5, lines 51-55, col. 14, lines 61-62).

Applicant’s arguments have been fully considered, but are not found to be persuasive. Applicant once again argues that Pluyter does not teach membranes formed from amphiphilic copolymers , but rather teaches lamellar vesicles which may have copolymers partially incorporated. This argument is not found to be persuasive since the membranes are still made of the copolymers along with the other vesicle forming structures

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and instant claim language does not require that the vesicle membranes are totally made from the copolymers.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1, 10, 12, 17 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Martin (5,891,468).

Martin discloses liposomes (nanocapsules) made from triblock polymers. The liposomes carry targeting ligand such as folic acid (note the abstract, figures, columns 7-11, examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant once again argues that Martin does not disclose vesicles having membranes formed from amphiphilic copolymers as required by the claims and that the vesicles taught by Martin are liposomes having diblock copolymer attached to thereto. This argument is not found to be persuasive for the following reasons. First of all, instant claim language does not exclude liposomes and other material contributing to the membrane as in Martin. The copolymers in Martin are part of the membranes.

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Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 9. Claims 1, 3-6, 9-14, 16-20 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/49387 by itself or in combination with Martin cited above.**

WO as discussed before, discloses nanoparticles containing vesicles. The vesicles are made of amphiphilic triblock copolymers. Either the core domain or the shell domain is hydrophilic. The polymerization is achieved photochemically. The nanoparticles further containing a pharmaceutically active agent (note the abstract, pages 4-5, 64, 72, 87, and claims). WO, although does not provide specific examples of the preparation of the nanoparticles having the pharmaceutical agents within, or particles with triblock polymers, it is suggestive of encapsulation of active agents in the core domain. Therefore, , it is deemed obvious to one of ordinary skill in the art to encapsulate the active agents in the core or prepare the nanoparticles from triblock polymer since WO provides guidance for such a preparation of particles. One of ordinary skill in the art would be motivated further to use triblock polymers in the preparation of the nanoparticles from the guidance also provided by Martin. The use of targeting ligand in WO is deemed obvious to one of

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ordinary skill in the art since these ligands would target the composition to the desired sites in the body. One of ordinary skill in the art would be motivated further to include a targeting ligand such as folic acid in WO since Martin shows its routine use in vesicle preparations containing triblock polymers.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments are based on the lack of teachings in WO of hollow core in the particles (based on the exhibits D-F). The examiner's reasoning is as follows. In WO 97, as pointed out before, the inventors teach that the central core need not be cross-linked and suggest that the active agent can be in the interior core in a dissolved state or in the form of a fine dispersion meaning that there are spaces in the core for the active agents (see page 86). Based on this, one can interpret that what is discussed in exhibits D and E is the achievement by the inventors of WO to make the center core totally empty as a cage structure whereas the particles in WO are only partially empty if they are not cross-linked. If the core in WO is totally solid, the inventors would not have discussed the encapsulation of the active agent either in the solubilized state or as a dispersion since there will not be space for the active agent. Applicant's arguments that Martin does not teach stabilizing the vesicles are not persuasive since WO teaches stabilization process by cross-linking. Therefore, applicant's arguments are not deemed to be persuasive.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

October 9, 2003